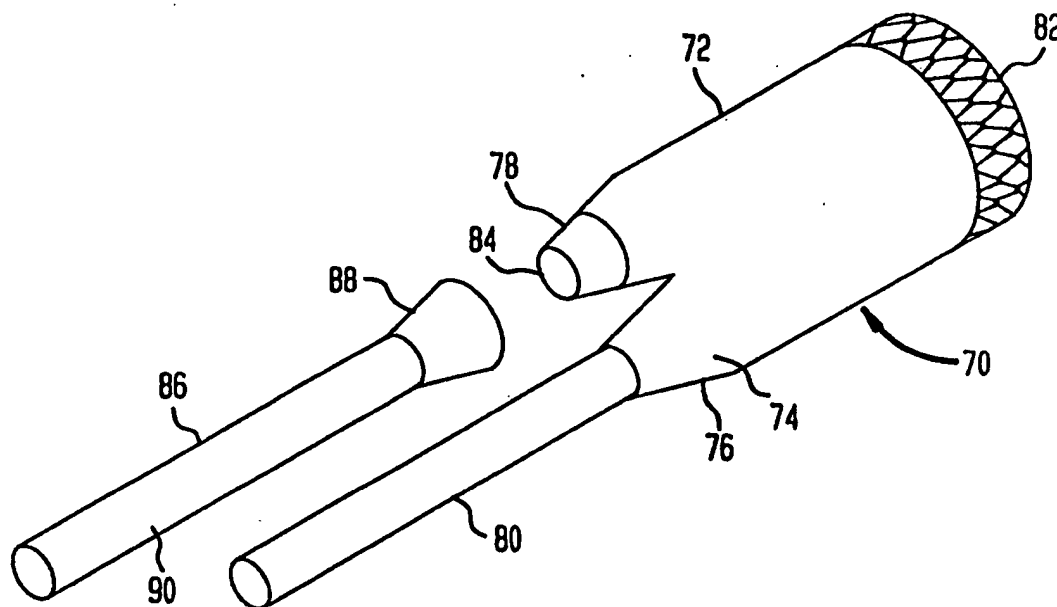




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(54) Title: BIFURCATED ENDOLUMINAL PROSTHESIS



(57) Abstract

The invention comprises: an introducer for delivering into the vasculature a straight or bifurcated stent or prosthesis; a method for delivering into the vasculature a straight or bifurcated stent or prosthesis; a method of treating an aneural disease using a bifurcated stent; an endoluminal stent having perpendicular hoop members, each hoop member formed of wire in a sinuous configuration, at least some of juxtaposed apices in neighboring hoops being secured to one another, such stents also forming axially aligned segments in straight stents, and segments of bifurcated stents in particular embodiments. Certain embodiments of such stents also include barbs, fabric covering and radiopaque markers.

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AMENDED CLAIMS

[received by the International Bureau on 27 September 1995 (27.09.95);
original claims 57, 58, 60 and 75-79 cancelled; original claims 1, 2, 8, 19, 42, 53, 56, 65, 72-74 and 80 amended;
remaining claims unchanged (16 pages)]

1 1. An introducer for delivering, into the
2 vasculature at an aneological bifurcation where a blood
3 vessel branches into two branched vessels, a bifurcated
4 endoluminal stent or prosthesis having a proximal portion
5 adapted to be disposed in said blood vessel and a distal
6 portion adapted to be disposed at least partially in one
7 of said two branched vessels, said introducer comprising:

8 (a) a tubular outer sheath;

9 (b) a proximal portion pusher disposed at
10 least partially within said outer sheath, said proximal
11 portion pusher being slideable with respect to said outer
12 sheath and adapted to engage and exert force on said
13 proximal portion of said bifurcated stent or prosthesis;
14 and

15 (c) a distal portion pusher disposed at least
16 partially within said proximal portion pusher, said
17 distal portion pusher being slideable with respect to
18 said proximal portion pusher and adapted to engage and
19 exert a force on said distal portion of said bifurcated
20 stent or prosthesis.

1 2. An introducer for delivering a bifurcated
2 endoluminal stent or prosthesis as claimed in claim 1
3 further comprising a balloon catheter, having a balloon
4 attached thereto, slideably disposed at least partially
5 within said distal portion pusher.

1 3. An introducer for delivering a bifurcated
2 endoluminal stent or prosthesis as claimed in claim 2
3 further comprising a hemostasis valve attached to the
4 distal end of said distal portion pusher.

1 4. An introducer for delivering a bifurcated
2 endoluminal stent or prosthesis as claimed in claim 2
3 further comprising wings on said outer sheath and said
4 proximal portion pusher.

1 5. An introducer for delivering a bifurcated
2 endoluminal stent or prosthesis as claimed in claim 2,

3 wherein said balloon catheter has an injection orifice
4 and an injection conduit therein.

1 6. An introducer for delivering a bifurcated
2 endoluminal stent or prosthesis as claimed in claim 2,
3 wherein said balloon catheter has an inflation orifice
4 and an inflation conduit therein.

1 7. An introducer for delivering a bifurcated
2 endoluminal stent or prosthesis as claimed in claim 2,
3 wherein said balloon catheter has a proximal end with a
4 nose cone attached thereto.

1 8. An introducer for delivering into the
2 vasculature at an aneological bifurcation where a blood
3 vessel branches into two branched vessels, an endoluminal
4 prosthesis having a proximal stent portion and a distal
5 stent portion, said introducer comprising:

6 (a) a tubular outer sheath;

7 (b) a proximal portion pusher slideably
8 disposed at least partially within said outer sheath and
9 having a proximal end adapted to contact said proximal
10 stent portion;

11 (c) a distal portion pusher slideably disposed
12 at least partially within said proximal portion pusher
13 and having a proximal end adapted to contact said distal
14 stent portion; and

15 (d) a balloon catheter, having a balloon
16 attached thereto, slideably disposed at least partially
17 within said distal portion pusher.

1 9. An introducer for delivering an
2 endoluminal stent into the vasculature at an aneological
3 bifurcation where a blood vessel branches into two
4 branched vessels, said introducer comprising:

5 (a) a tubular outer sheath;

6 (b) a proximal portion pusher disposed at
7 least partially within said outer sheath and having a

8 proximal end adapted to contact a distal end of said
9 stent; and

10 (c) a distal portion pusher disposed at least
11 partially within said proximal portion pusher and secured
12 to said proximal portion pusher such that proximal ends
13 of said distal portion pusher and said proximal portion
14 pusher are flush with one another.

1 10. A method for delivering a bifurcated
2 endoluminal stent or prosthesis having a proximal portion
3 and a first distal portion into the vasculature at an
4 aneological bifurcation where a blood vessel branches
5 into a first branched vessel and a second branched
6 vessel, said method comprising the steps of:

7 (a) inserting a first introducer containing
8 said stent or prosthesis into the vasculature to a
9 predetermined delivery location, said first introducer
10 comprising an outer sheath, a proximal portion pusher,
11 and a distal portion pusher;

12 (b) withdrawing said outer sheath of said
13 first introducer while maintaining said proximal portion
14 pusher in a fixed position until said proximal portion of
15 said stent or prosthesis is deployed from said first
16 introducer into said blood vessel;

17 (c) withdrawing said outer sheath and said
18 proximal portion pusher while maintaining said distal
19 portion pusher in a fixed position until said first
20 distal portion of said stent or prosthesis is deployed
21 from said first introducer at least partially into said
22 first branched vessel; and

23 (d) withdrawing said first introducer from the
24 vasculature.

1 11. A method for delivering a bifurcated
2 endoluminal stent or prosthesis as claimed in claim 10
3 further comprising the steps of:

4 (a) inserting into the vasculature a second
5 introducer containing a second distal portion of said

6 stent or prosthesis and comprising an outer sheath and a
7 pusher;

8 (b) withdrawing said outer sheath of said
9 second introducer while maintaining said pusher of said
10 second introducer in a fixed position until said second
11 distal portion of said stent or prosthesis is deployed
12 from said second introducer such that a proximal end of
13 said second distal portion securely connects to said
14 proximal portion of said stent or prosthesis, and such
15 that a distal end of said second distal portion extends
16 at least partially into said second branched vessel; and

17 (c) withdrawing said second introducer from
18 the vasculature.

1 12. A method for delivering a bifurcated
2 endoluminal stent or prosthesis as claimed in claim 10
3 wherein said first introducer further comprises a balloon
4 catheter having a balloon attached thereto and said
5 method further comprises the step of inflating said
6 balloon to at least partially block blood flow in said
7 blood vessel after inserting said first introducer into
8 the vasculature.

1 13. A method for delivering, into the
2 vasculature at an aneological bifurcation where a blood
3 vessel branches into two branched vessels, an endoluminal
4 prosthesis having a proximal stent portion, and a distal
5 stent portion, said method comprising the steps of:

6 (a) inserting an introducer containing said
7 prosthesis into the vasculature to a predetermined
8 delivery location, said introducer comprising an outer
9 sheath, a proximal stent portion pusher, a distal stent
10 portion pusher, and a balloon catheter having a balloon
11 attached thereto;

12 (b) inflating said balloon to at least
13 partially block blood flow in said blood vessel;

14 (c) withdrawing said outer sheath of said
15 introducer while maintaining said proximal stent portion

16 pusher in a fixed position until said proximal stent
17 portion of said prosthesis is deployed from said
18 introducer into said blood vessel;

19 (d) withdrawing said outer sheath and said
20 proximal stent portion pusher while maintaining said
21 distal stent portion pusher in a fixed position until
22 said distal stent portion of said prosthesis is deployed
23 from said introducer into said blood vessel; and

24 (e) withdrawing said introducer from the
25 vasculature.

1 14. A method of treating an angeological
2 disease at a bifurcation site where a blood vessel
3 branches into a first branched vessel and a second
4 branched vessel comprising the steps of:

5 (a) disposing in said blood vessel a proximal
6 portion of an endoluminal stent;

7 (b) directing blood flow from said blood
8 vessel into said first branched vessel through a first
9 distal portion of said endoluminal stent, said first
10 distal portion being connected to said proximal portion
11 and extending into said first branched vessel; and

12 (c) directing blood flow from said blood
13 vessel into said second branched vessel through a second
14 distal portion of said endoluminal stent, said second
15 distal portion being connected to said proximal portion
16 and extending into said second branched vessel,

17 wherein said stent portions are substantially
18 completely covered by a biocompatible fabric graft.

1 15. A method of treating an angeological
2 disease at a bifurcation site where a blood vessel
3 branches into a first branched vessel and a second
4 branched vessel as claimed in claim 14 wherein said
5 disease is stenosis.

1 16. A method of treating an angeological
2 disease at a bifurcation site where a blood vessel
3 branches into a first branched vessel and a second

4 branched vessel as claimed in claim 14 that further
5 comprises covering any of said proximal portion, said
6 first distal portion, and said second distal portion with
7 fabric.

1 17. A method of treating an angeological
2 disease at a bifurcation site where a blood vessel
3 branches into a first branched vessel and a second
4 branched vessel as claimed in claim 16 wherein said
5 disease is an aneurysm.

1 18. A method of treating an angeological
2 disease at a bifurcation site where a blood vessel
3 branches into a first branched vessel and a second
4 branched vessel as claimed in claim 16 wherein said
5 disease is an occlusion.

1 19. An endoluminal stent comprising a
2 plurality of hoops which are axially displaced in a
3 tubular configuration along a common axis, each of said
4 hoops

5 (a) being formed by a substantially complete
6 turn of a sinuous wire having apices, and

7 (b) having a circumference that lies in a plane
8 substantially perpendicular to the longitudinal axis of
9 said stent;

10 wherein apices of adjacent hoops are juxtaposed
11 in an abutting relationship to one another, and at least
12 two juxtaposed apices are directly connected to one
13 another by a securing means that permits limited relative
14 movement therebetween.

1 20. A stent as recited in claim 19 in
2 combination with one or more additional stent segments.

1 21. A stent as recited in claim 20 wherein at
2 least one of said additional stent segments comprises a
3 plurality of hoops which are axially displaced in a
4 tubular configuration along a common axis, each of said
5 hoops

6 (a) being formed by a substantially complete
7 turn of a sinuous wire having apices, and

8 (b) having a circumference that lies in a plane
9 substantially perpendicular to the longitudinal axis of
10 said stent;

11 wherein apices of adjacent hoops are juxtaposed
12 to one another, and at least two juxtaposed apices are
13 connected by a securing means.

1 22. A stent as recited in claim 20 wherein
2 said one or more additional segments are axially aligned
3 with one another.

1 23. A stent as recited in claim 20 wherein
2 said one or more additional segments are secured to one
3 another by connecting means connecting at least some of
4 the apices of hoops at mating ends of said stent and said
5 additional segments.

1 24. A stent as recited in claim 20 wherein
2 adjacent hoops are of the same diameter.

1 25. A stent as recited in claim 20 wherein
2 adjacent hoops are of a different diameter.

1 26. A stent as recited in claim 22 wherein
2 said axially aligned segments are connected to one
3 another by a tubular fabric element.

1 27. A stent as recited in claim 20 wherein a
2 first additional segment is axially parallel to, but non-
3 common co-axial with, said stent.

1 28. A stent as recited in claim 27 further
2 comprising a second additional segment axially parallel
3 to said stent, but non-co-axial with either said stent or
4 said first additional stent segment.

1 29. A stent as recited in claim 28 wherein at
2 least one of said additional stent segments is of
3 frustoconical shape and is further combined with an
4 additional stent segment, one end of which includes a
5 mating frustoconical shape.

1 30. At stent as recited in claim 29, wherein
2 said mating frustoconical stent segments are adapted to
3 be separately placed in a bifurcated artery and then, by
4 expansion of one of said frustoconical stent segments,
5 secured to one another

1 31. An endoluminal stent as claimed in claim
2 19 wherein said hoops are formed of a single continuous
3 wire.

1 32. An endoluminal stent as claimed in claim
2 19 wherein said securing means is a suture.

1 33. An endoluminal stent as claimed in claim
2 32 wherein said suture is a tied loop of thermoplastic
3 material.

1 34. An endoluminal stent as claimed in claim
2 19 wherein said securing means is a ring.

1 35. An endoluminal stent as claimed in claim
2 19 wherein said securing means is a staple.

1 36. An endoluminal stent as claimed in claim
2 19 wherein said securing means is wire twisted into loop.

1 37. An endoluminal stent as claimed in claim
2 36 wherein said wire is nitinol.

1 38. An endoluminal stent as claimed in claim
2 19 wherein said securing means is bead of thermoplastic
3 material.

1 39. An endoluminal stent as claimed in claim
2 19 wherein the plane of the circumference at each
3 longitudinal end of the stent is square to the
4 longitudinal axis of the stent.

1 40. An endoluminal stent as claimed in claim
2 19 wherein said stent is at least partially covered in
3 fabric.

1 41. An endoluminal stent as claimed in claim
2 31 wherein said wire is nitinol.

1 42. A method of making an endoluminal stent
2 having a plurality of hoops which are axially displaced
3 in a tubular configuration, each of said hoops being
4 formed by a substantially complete turn of a sinuous wire
5 with apices and having a circumference that lies in a
6 plane substantially perpendicular to the longitudinal
7 axis of the stent, said method comprising the steps of:

8 (a) winding a wire in a zig-zag pattern around
9 a mandrel having a plurality of upstanding pins defining
10 said zig-zag pattern to form a first hoop having apices
11 and a circumference that lies in a plane substantially
12 perpendicular to the longitudinal axis of said mandrel;

13 (b) longitudinally displacing said wire with
14 respect to the axis of said mandrel;

15 (c) winding said wire in a zig-zag pattern
16 around a plurality of upstanding pins on said mandrel to
17 form a second hoop, adjacent said first hoop, having
18 apices juxtaposed to the apices of said first
19 circumferential hoop and a circumference that lies in a
20 plane substantially perpendicular to the longitudinal
21 axis of said mandrel;

22 (d) longitudinally displacing said wire with
23 respect to the axis of said mandrel;

24 (e) repeating steps (a)-(d) to form additional
25 hoops until a predetermined number of hoops are formed;

26 (f) annealing said wire on said mandrel;

27 (g) cooling said wire on said mandrel;

28 (h) removing said wire from said mandrel; and

29 (i) securing together at least two juxtaposed
30 abutting apices of adjacent hoops to one another to
31 permit limited relative movement therebetween.

1 43. A method of determining rotational
2 orientation of an endoluminal prosthesis during insertion
3 of said prosthesis into the vasculature of a body
4 comprising the steps of disposing a radiopaque marker of

5 predetermined shape on said prosthesis, detecting said
6 marker using a detector outside the body to create an
7 image of said marker, and adjusting the rotational
8 position of said prosthesis based on said image.

1 44. A method as claimed in claim 43 wherein
2 said radiopaque marker comprises a radiopaque element
3 attached to one end of said stent.

1 45. A method as claimed in claim 44 wherein
2 said element is a platinum wire.

1 46. A method as claimed in claim 44 wherein
2 said element is a gold wire.

1 47. A method as claimed in claim 43 wherein
2 said radiopaque marker comprises a radiopaque tube
3 disposed around a part of said stent.

1 48. A method as claimed in claim 47 wherein
2 said tube is platinum.

1 49. A method as claimed in claim 47 wherein
2 said tube is gold.

1 50. Apparatus for delivering an endoluminal
2 stent or prosthesis into the vasculature comprising:

3 (a) an introducer having a first portion of a
4 lock fitting on a distal end thereof; and

5 (b) a cartridge having an inner tubular member
6 containing said stent or prosthesis in a compressed
7 state, an outer sheath, and a second portion of said lock
8 fitting;

9 wherein said first portion of said lock fitting
10 on said introducer mates with said second portion of said
11 lock fitting on said cartridge to prevent relative
12 movement of said introducer and said cartridge.

1 51. Apparatus as claimed in claim 50 wherein
2 said lock fitting is a Luer lock.

1 52. Apparatus as claimed in claim 50 further
2 comprising a hemostasis valve on said introducer and a
3 pusher adapted to push said compressed stent or

4 prosthesis through said cartridge, through said
5 introducer, and into the vasculature.

1 53. A bifurcated prosthesis comprising:

2 a bifurcated stent having a proximal stent
3 portion adapted to be disposed within a blood vessel in
4 juxtaposition with a bifurcation, a first distal stent
5 portion in direct contact with said proximal stent
6 portion and adapted to extend across the bifurcation into
7 a first branched blood vessel, and a second distal stent
8 portion in direct contact with said proximal stent
9 portion and adapted to allow blood to flow from the
10 proximal portion into a second branched vessel,

11 a tubular graft layer formed from a
12 biocompatible fabric disposed in juxtaposition with said
13 bifurcated stent, and

14 barbs disposed adjacent to said fabric to
15 secure said prosthesis to said blood vessel.

1 54. A bifurcated endoluminal stent as claimed
2 in claim 53 wherein said barbs are attached to said stent
3 and extend through said fabric.

1 55. A bifurcated endoluminal stent as claimed
2 in claim 53 wherein said barbs are attached to an outside
3 surface of said fabric.

1 56. A bifurcated stent for use in
2 juxtaposition with an anatomical bifurcation of a blood
3 vessel into two branched vessels comprising a proximal
4 stent portion adapted to be disposed within said blood
5 vessel in juxtaposition with said bifurcation, a distal
6 stent portion formed integrally with said proximal stent
7 portion and adapted to extend across the bifurcation into
8 one of the branched vessels, and a distal stent segment
9 joined to said proximal portion by a joining means and
10 adapted to allow blood to flow from the proximal portion
11 into the other branched vessel; each of said stent
12 portions and said stent segments being a sinuous wire
13 formed into a substantially tubular configuration, said
14 wire defining a plurality of hoops such that the plane of

15 the circumference of each hoop is disposed substantially
16 perpendicular to the longitudinal axis of the stent
17 portion or segment, wherein said joining means comprises
18 a frustoconical male engaging portion on a proximal end
19 of said distal stent segment adapted to fit within and
20 engage a frustoconical female cooperating portion on a
21 distal end of said proximal stent portion.

1 57. (Cancelled)

1 58. (Cancelled)

1 59. A bifurcated stent as claimed in claim 58
2 wherein said stent is made from a shape memory nitinol
3 (nickel/titanium) wire having a tubular configuration
4 slightly greater diameter than the diameter on the blood
5 vessel on which the stent intended to be used.

1 60. (Cancelled)

1 61. A bifurcated stent as claimed in claim 60
2 wherein each hoop comprises a substantially complete turn
3 of the wire.

1 62. A bifurcated stent as claimed in claim 60
2 wherein the plane of the circumference of the hoop at
3 each longitudinal end of the stent is square to the
4 longitudinal axis of the stent.

1 63. A stent as claimed in claim 60 further
2 comprising securing means for securing an apex of the
3 sinuous wire in one hoop to a juxtaposed apex of a
4 neighboring hoop so that each hoop is supported by its
5 neighbors.

1 64. A bifurcated stent as claimed in claim 63
2 wherein said securing means comprises a loop element to
3 tie the juxtaposed apices together.

1 65. Stent apparatus for use in juxtaposition
2 with an aneological bifurcation; said apparatus
3 comprising a first bifurcated stent comprising a proximal
4 stent portion adapted to be disposed within a blood
5 vessel in juxtaposition with a bifurcation, a first
6 distal stent portion adapted to extend across the

7 bifurcation into one of the branched blood vessels, and a
8 second distal stent portion adapted to allow blood to
9 flow from the proximal portion into the other branched
10 vessel; and a second stent adapted to extend in the other
11 branched blood vessel; wherein said second distal stent
12 portion comprises a frustoconical female cooperating
13 portion and said second stent comprises a frustoconical
14 male engaging portion adapted to fit within and engage
15 said female cooperating portion; the arrangement being
16 such that, in use, said first bifurcated stent can be
17 joined in situ to the second stent.

1 66. Stent apparatus as claimed in claim 65
2 wherein the proximal end of said first stent is flared
3 radially outwardly towards its extremity to engage the
4 endoluminal surface of the blood vessel, thereby to
5 resist longitudinal movement of the first stent in
6 service.

1 67. A bifurcated prosthesis comprising:
2 a bifurcated stent having a proximal stent
3 portion adapted to be disposed within a blood vessel in
4 juxtaposition with a bifurcation of said blood vessel
5 into two branched vessels, a first distal stent portion
6 adapted to extend across the bifurcation into one of said
7 branched vessels, and a second distal stent portion
8 adapted to allow blood to flow from the proximal portion
9 into the other branched vessel, and

10 a tubular graft layer formed from a bio-
11 compatible fabric disposed in juxtaposition with said
12 bifurcated stent.

1 68. A bifurcated prosthesis as claimed in
2 claim 67 wherein said graft layer is disposed internally
3 of the stent.

1 69. A bifurcated prosthesis as claimed in
2 claim 67 wherein the graft layer is secured to the stent
3 by loop elements.

1 70. A bifurcated prosthesis as claimed in
2 claim 67 wherein the bio-compatible fabric comprises a

3 fabric selected from the group consisting of polyester
4 fabric and polytetrafluoroethylene fabric.

1 71. A bifurcated prosthesis as claimed in
2 claim 67 wherein said fabric is a fabric selected from
3 the group consisting of a woven polyester fabric and a
4 warp knitted polyester fabric.

1 72. A stent joining means for joining two
2 endoluminal stents one to the other to define a
3 continuous lumen through the two stents, said stent
4 joining means comprising:

5 a first stent including a frustoconical male
6 engaging portion which can be compressed radially
7 inwardly; and

8 a second stent including frustoconical female
9 cooperating portions;

10 wherein the frustoconical male engaging portion
11 can be entered into the frustoconical female cooperating
12 portion in a radially compressed state and thereafter
13 caused or allowed to expand in the frustoconical female
14 cooperating portion; the arrangement being such that in
15 service the inter-engagement of the frustoconical male
16 engaging portion and the frustoconical female cooperating
17 portion so as to resist longitudinal separation of the
18 two stents one from the other.

1 73. A stent joining means as claimed in claim
2 72 wherein said first stent includes a proximal
3 frustoconical male engaging portion.

1 74. A stent joining means as claimed in claim
2 72 wherein said second stent includes a distal
3 frustoconical female cooperating portion.

1 75. (Cancelled)

1 76. (Cancelled)

1 77. (Cancelled)

1 78. (Cancelled)

1 79. (Cancelled)

1 80. A stent joining means as claimed in claim
2 72 wherein said frustoconical male engaging portion is
3 resiliently compressible in a radially inwards direction
4 such that in a radially compressed state the male
5 engaging portion is capable of self re-expansion to
6 engage in the frustoconical female cooperating portion.

1 81. A stent joining means as claimed in claim
2 72 wherein each of said first and second stents is
3 resiliently compressible.

1 82. A stent joining means as claimed in claim
2 72 wherein said second stent has two transversely spaced
3 distal female cooperating portions.

1 83. A stent joining means as claimed in claim
2 82 wherein each of said two transversely distal female
3 cooperating portions is adapted for connection to a first
4 male stent which, in use, extends across a bifurcation in
5 a blood vessel into a respective branched blood vessel.

1 84. A stent joining means as claimed in claim
2 72 wherein the proximal end of said second stent is
3 flared radially outwardly towards its extremity to engage
4 the endoluminal surface of the blood vessel thereby to
5 resist longitudinal movement of the second stent in
6 service.

1 85. A stent joining means as claimed in claim
2 72 wherein each of said first and second stents comprises
3 a sinuous wire formed into a tubular configuration.

1 86. A stent joining means as claimed in claim
2 85 wherein each of said first and second stents is formed
3 from a shape memory nitinol (nickel/titanium) wire.

1 87. A stent joining means as claimed in claim
2 72 wherein said second stent is adapted to extend across
3 a bifurcation in a blood vessel such that in use the
4 proximal end of the second stent is disposed proximally
5 of the bifurcation, and the distal end is disposed in one
6 of the branched blood vessels; said distal female
7 cooperating portion is disposed intermediate said

8 proximal and distal ends, and said first stent is adapted
9 to extend in the other branched blood vessel.

1 88. A method of joining a first endoluminal
2 stent with a second endoluminal stent within the
3 vasculature of a body comprising the steps of inserting
4 an end of said first stent at least partially into an end
5 of said second stent, and allowing said end of said first
6 stent to expand and contact said end of said second
7 stent.

1 89. An endoluminal stent formed within the
2 vasculature of a body according to a process comprising
3 the steps of inserting an end of a first stent portion at
4 least partially into an end of a second stent portion,
5 and allowing said end of said first stent portion to
6 expand and contact said end of said second stent portion.

1 90. An endoluminal prosthesis comprising a
2 stent as claimed in claim 89, and a tubular graft layer
3 formed from a bio-compatible fabric disposed in
4 juxtaposition with said stent.

1 91. A bifurcated prosthesis as claimed in
2 claim 67 wherein said graft layer is disposed on the
3 external surface of the stent.